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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,962	08/22/2003	David Farrar	00167-482001 / 02-31-0454	8400
26166 FISH & RICHA	7590 04/05/2007 ARDSON P.C.		EXAM	INER
SMITH & NEP	HEW, INC.	·	IZQUIERDO), DAVID A
	1450 BROOKS ROAD MEMPHIS, TN 38116		ART UNIT	PAPER NUMBER
,			3738	
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVER	Y MODE
3 MONTHS		04/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)		
	10/645,962	FARRAR ET AL.		
Office Action Summary	Examiner	Art Unit		
	David A. Izquierdo	3738		
The MAILING DATE of this communication Period for Reply	appears on the cover sheet w	ith the correspondence address		
A SHORTENED STATUTORY PERIOD FOR REWHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication - If NO period for reply is specified above, the maximum statutory properties to reply within the set or extended period for reply will, by some Any reply received by the Office later than three months after the rearned patent term adjustment. See 37 CFR 1.704(b).	G DATE OF THIS COMMUNION R 1.136(a). In no event, however, may a rown. eriod will apply and will expire SIX (6) MON tatute, cause the application to become Alexandre.	CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed on	77 January 2007.			
2a) This action is FINAL . 2b)⊠	This action is non-final.			
3) Since this application is in condition for all	oplication is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice und	der <i>Ex par</i> te Quayle, 1935 C.D). 11, 453 O.G. 213.		
Disposition of Claims				
4) ☐ Claim(s) 1,8-11,22-24,31,32 and 37 is/are 4a) Of the above claim(s) is/are with 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1,8-11,22-24,31, 32 and 37 is/are 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction a	e rejected.			
Application Papers				
9) The specification is objected to by the Example 1	miner.			
10) The drawing(s) filed on is/are: a)	accepted or b) ☐ objected to	by the Examiner.		
Applicant may not request that any objection to				
Replacement drawing sheet(s) including the co	•			
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of: 1. Certified copies of the priority docur 2. Certified copies of the priority docur 3. Copies of the certified copies of the application from the International Bu	ments have been received. ments have been received in A priority documents have beer	Application No		
* See the attached detailed Office action for a	a list of the certified copies not	received.		
And A country				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-94)	· —	Summary (PTO-413) (s)/Mail Date		

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date ___

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

5) Notice of Informal Patent Application

6) Other: ____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 8-11, 22-24, 31, 32, and 37 have been considered but are most in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1, 8-11, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Draenert (U.S Patent Number 4,373,217).
- 3. Draenert discloses a tissue replacement material comprised of a ceramic composition and a polymeric scaffold wherein the ceramic degrades in vivo and the polymer scaffold remains and further provides pores to facilitate tissue ingrowth once the ceramic has been fully resorbed (col. 3, lines 1-27). The tissue replacement material of Draenert is further provides an antibiotic admixed within the composition (Col. 6, lines 32-37).

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 22-24 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al. ("Sambrook") (WIPO 02/15881) as identified by Applicant within the

Application/Control Number: 10/645,962 Page 3

Art Unit: 3738

Information Disclosure Statement in view of Dillon (U.S. Patent Number 4,849,285) and Brown (U.S. Patent Number 6,583,232)

- 6. Sambrook discloses a medical device comprised of two components, a porous ceramic scaffold wherein the pores have a diameter between 20 and 200 microns and the scaffold has a porosity of between 10 percent and 90 percent (page 3, paragraph 3) and a polymeric material which fills the pores of the ceramic scaffold wherein the polymeric material comprised a higher rate of degradation than the ceramic scaffold. The combination of the two layer provides a device which is substantially non-porous prior to implantation and allows for the ingrowth of tissue after implantation (page 8, paragraphs 4-5).
- 7. Furthermore, Sambrook discloses a polymeric layer comprising a therapeutic additive comprising a higher rate of degradation than the ceramic scaffold (pages 13-14).
- 8. However Sambrook fails to disclose the use of tricalcium phosphate or polyglyconate B as the ceramic and polymer within the medical device. It is well known in the art to use tricalcium phosphate and polyglyconate B within tissue replacement devices however the disclosures of Dillon and Brown are provided to demonstrate the use of these compounds. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Sambrook with the compounds as provided by Dillon and Brown. The motivation to combine the compounds of Dillon and Brown with the device of Sambrook being that tricalcium phosphate is biocompatible, promotes tissue ingrowth and is bioresorbable (Dillon: col. 1, lines 35-40) and polyglyconate B degrades rapidly *in-vivo* to provide porosity and allow for tissue ingrowth (Brown: col. 3, lines 8-15).

Application/Control Number: 10/645,962 Page 4

Art Unit: 3738

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Izquierdo whose telephone number is 571-272-1943.

The examiner can normally be reached on Monday through Friday from 8:00 am until 4:30 pm.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Izquierdo

Patent Examiner

TECHNOLOGY CENTER 3777